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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,977	09/25/2003	Russell Beavis	1062/D44	8101
2101	7590	10/19/2005	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618				SAINT SURIN, JACQUES M
ART UNIT		PAPER NUMBER		
		2856		

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,977	BEAVIS ET AL. <i>[Signature]</i>	
	Examiner	Art Unit	
	Jacques M. Saint-Surin	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-13 and 15-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-13 and 15-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This Office Action is responsive to the amendment of 07/28/05.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1-9, 11-13 and 15-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkins et al. (US Patent 5,641,892) in view of Denyer et al. (US Patent Application Publication US 2003/0146300 A1).

Regarding claim 1, Larkins discloses an apparatus (Fig. 1 depicts an acoustically resonant system) comprising:

a chamber comprising a gas region and a fluid region (chamber 85 is occupied by a measurement gas and IV fluid of an isolatable region 50);
an acoustic source (speaker 81, as shown in Fig. 1) configured to be acoustically coupled to a variable-volume chamber (chamber 85-87) as shown in Fig. 1);
a microphone (service microphone 83 as shown in Fig. 1) configured to be acoustically coupled to the variable-volume chamber (85-87); and
a processor (controller as shown in Fig. 1) configured to receive a signal from the microphone, and further configured to determine a volume of the variable-volume chamber (85-87) based on the received signal, the processor being embedded on a printed circuit board (the controller of Larkins as shown in Fig. 1 is inherently embedded in a printed circuit board). However, Larkins does not disclose an atomizer

in fluid communication with the fluid region of the chamber for aerosolizing fluid delivered from the fluid region. Denyer discloses a power supply 14 is used to power the atomizer since power is required to drive the aerosolization (see: paragraph 0040, lines 1-2). Denyer further discloses a nebulizer 1 generates an aerosol 2 of a drug preparation through a mesh plate 3 by using an ultrasonic transducer 4 and a substance to be atomized into an aerosol 2 is in fluid contact with the rear face of the mesh plate, see: paragraph 0035, lines 3-7 and 10-13. It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize in Larkins the techniques of Denyer because it would allow a unit dose of vial of a substance to be nebulized to be poured into the reservoir, but only the metered volume of the metering chamber to be nebulized during the treatment since the remainder or excess of the substance is retained in the second chamber thereby, providing the advantages of being relatively simple in construction, and allows the excess drug to be retained in the second chamber only once the barrier has been put in place.

Regarding claim 2, Larkins in view of Denyer shows acoustic source speaker 81 that is inherently embedded in a printed circuit board.

Regarding claim 3, Larkins in view of Denyer shows microphone 82 that is inherently embedded on the printed circuit board.

Regarding claim 4, Larkins in view of Denyer shows in Fig. 1 shows the printed circuit board is disposed within a housing, and wherein the printed circuit board defines a first volume and a second volume within the housing (note that microphone 83 is

acoustically connected to first volume (chamber 87 and microphone 82) is acoustically connected to second volume (back chamber 86).

Regarding claims 5-6, Larkins in view of Denyer discloses if a change in the front chamber's volume is indicated, then the controller generates a signal indicating the presence of a bubble. Preferably, this signal causes valve 6 to open, while valve 7 remains closed, and then causes the pressure source 42 to increase the pressure against the membrane to cause the IV fluid in the isolatable region 50, including the bubble 51, to be forced back to the IV source. Furthermore, If no change in the front chamber's volume is indicated, then the controller causes the valve 7 to open, so that IV fluid may be delivered to the patient. The amount that valve 7 (or another valve downstream of the isolatable region) is opened and the amount of pressure applied by the pressure source 42 are controlled so as to control the flow rate of IV fluid to the patient, see: col. 7, lines 26).

Regarding claim 7, Larkins in view of Denyer discloses a controller is also provided for controlling the valves, the resonance-detection means, and the pressure-changing means, and for generating a signal indicating the presence of a bubble. Preferably, the controller also includes means for determining the volume of the measurement gas in the region's first portion based on a measured resonant frequency, see: col. 1, lines 53-60.

Regarding claim 8, as discussed above, it is similar in scope with claim 1. Therefore, it is rejected for the reasons set for that claim. Furthermore, Larkins shows

in Fig. 1 first microphone 83 and second microphone 82. In addition, the processor (controller of Fig. 1) inherently calculates the changes in the third volume.

Regarding claims 9, 17 and 25, Larkins in view of Denyer discloses a printed circuit board that includes a processor (controller of Fig. 1).

Regarding claims 11, 19 and 26, Larkins in view of Denyer shows an electrical model in Fig. 2 which indicates the inherency of the inner layer configured to pass electrical signals.

Regarding claims 12, 20 and 27, Larkins in view of Denyer shows in Fig. 1 first microphone 83, second microphone 82 and a controller is also provided for controlling the valves, the resonance-detection means, and the pressure-changing means, and for generating a signal indicating the presence of a bubble, see; col. 1, lines 53-60.

Regarding claim 13-14, 21 and 28, Larkins in view of Denyer discloses the back chamber's microphones 82 is used to detect the response of the system to the acoustic energy created by the speaker 81, and the response detected by the service chamber's microphone 83 is used to calibrate continuously the speaker 81 and the back chamber's microphone 82, see: col. 3, lines 6-10).

Regarding claims 15, 22 and 29, Larkins in view of Denyer discloses a speaker 81, preferably of the piezo-crystal type although any suitable electro-acoustical transducer may be used, to introduce acoustic energy at various frequencies into the system, see: col. 2, lines 65-67 and col. 3, line 1.

Regarding claims 16 and 24, as discussed above, they are similar in scope with claim 8 and therefore they are rejected for the reasons set forth for that claim.

Regarding claims 23 and 30, Larkins in view of Denyer shows in Fig. 1 third volume front chamber 85, fluid filled diaphragm 50, membrane 41, valves 6 and 7.

Regarding claim 18, Larkins in view of Denyer shows in Fig. 1 the second volume 86 is acoustically coupled to the third volume 85 by a port 84.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Larkins et al. (US Patent 5,641,892) in view of Denyer et al. (US Patent Application Publication US 2003/0146300 A1) and further in view of Gray et al. (US Patent 6,808,369).

Regarding claim 10, Larkins does not disclose a removable cassette. Gray discloses a disposable cassette is securely mounted onto the fluid flow control device 200, see: col. 3, lines 13-15. It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize in Larkins in view of Denyer the disposable cassette of Gray because fluid communication with the cassette 201 is maintained from a heated solution bag 202 via a solution inlet line 203 and is also maintained to a distal end 208 of an outlet line 204 thereby providing the advantages of having a volume determination of the fluid in an efficient manner.

Response to Arguments

5. Applicant's arguments with respect to claims 1-13 and 15-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacques M. Saint-Surin whose telephone number is (571) 272-2206. The examiner can normally be reached on Mondays through Fridays 10:30 A.M. -7:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272 2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

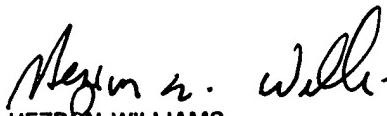
Art Unit: 2856

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the
Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jacques M. Saint-Surin

October 15, 2005


HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800